REMARKS/ARGUMENTS

This is in response to the official action of February 25, 2004. The allowability of claims 37-39 is acknowledged. Those claims have been rewritten in independent form. Independent claim 29 has been amended. Reconsideration of the rejected claims is requested for the reasons discussed, following the discussion of the invention and the cited references, immediately below.

Applicants' Invention

Applicants' invention relates to an arrangement for therapeutic treatment of degenerative osteoarthritis and, particularly, to the treatment by removal of fragments such as bone, articular cartilage, and calcium pyrophosphate crystals that form on or adhere to the interior surfaces of an affected joint in the body. The fragments irritate and inflame the joint, causing discomfort. In one aspect of the invention the device includes an arthroscopically insertable shaft, relatively rigid for most of its length, with a debridement tip mounted to the distal end of the shaft. The debridement tip is more flexible than the relatively rigid portion of the shaft and includes a flexible debridement surface. The rigidity of the shaft is such as to enable the shaft to be manipulated from its proximal end to bring the debridement tip to bear forcefully against selected internal regions of the joint. The debridement tip and surface have sufficient abrasion characteristics to enable arthroscopic debridement of irritant fragments while being sufficiently resilient and flexible to minimize trauma to the joint. The fragments, having been freed from the interior surfaces of the joint, then can be removed from the joint, as

by flushing. In another aspect of the invention, the shaft and debridement tip are provided with flow passages through which irrigation of the liquid may be provided to facilitate flushing the interior of the joint, to flush the irritation-causing fragments from the joint.

The system with which the device is used includes a reservoir containing an irrigation liquid, such as saline, and is connected by flexible tubing to a hand piece by which the delivery of irrigation liquid from the reservoir to the joint can be controlled. The tip is adapted to be inserted, arthroscopically, into the joint.

THE CITED REFERENCES

U.S. Patent 5,535,756 (Parasher)

The Parasher '756 patent is directed to a flexible catheter adapted to be advanced into and through a duct in the body, such as "...the common bile duct, the pancreatic duct, and any of a number of other duct-like organs and the like, such as, for example, the esophagus, the stomach, the large bowel, the lungs, the uterus, the urator, the kidney, etc..." (2:35-39). The catheter is elongated and flexible and has a brush located adjacent its distal end. The catheter is adapted to be passed over a guidewire for guiding the catheter into and through the duct. (2:41-49). The brush is configured to perform a cytology procedure, that is, to collect cells and tissue samples by pushing and pulling the brush and forth over the inner wall of the duct. "The bristles of the brush collect sample scrapings of tissue and brushings of cells at the selected area. The end of the catheter with the brush is withdrawn from the duct... The scrapings of tissue and cells that cling to the brush can then be removed and analyzed by standard

methods."(3:20-32). The bristles are adapted to have enlarged or hooked ends so that they will collect and trap cell and tissue samples.

U.S. Patent 5,370,653 (Cragg)

The Cragg patent discloses a thrombectomy device adapted to remove soft-newly formed thrombus (blood clot) from a blood vessel by applying a dissolving agent, such as streptokinase or eurokinase, to the clot and using a soft, flexible rotating brush to mix the dissolving agent with the thrombus to accelerate dissolving of the thrombus in sito. Such blood clots are said to be ... soft and jelly-like in consistency" (1:35-36). It is said to be among the principle objects of the Cragg device "... to provide a thrombectomy apparatus and method which provides for the dissolution of a soft, recently formed thrombus in sito without the necessity of depending on aspirating or trapping and removing fragments."

Fig. 3 of the Cragg patent illustrates the device.

The device includes a brush 10 attached at the distal end of a rotatable drive shaft that is housed within a catheter 30. The drive shaft is rotated by a drive motor assembly 50 at the proximal end of the device. The drive shaft is said to be "... a solid wire or a cable of stranded wire that has an outside diameter of about 0.50 mm and a length of about 60-120 cm. The entire drive shaft 14 and attached brush 10 are rotated by the motor at speeds of about 10-300 rpm" (6:3-18). The side port extension 38 is attached to the catheter 30 and provides passageway through which the dissolving agent can be caused to flow into the catheter 30 and delivered to the duct through the

catheter 30 as suggested by the arrows 32. The dissolving agent is said to be infused "... at about 2-250 ml/hour" (5:33).

In the operation of the device, "[a]s the bristles sweep over and through the thrombolytic mass, they separate strands or fibrin of the thrombus, so that they are progressively and repetitively mixed with and exposed to the infused dissolving agent. This mixing exposure speeds the operation of the dissolving agent and reduces the total amount introduced. After a period of such treatment, the thrombus becomes completely dissolved" (5:33-40).

CLAIM REJECTIONS – ANTICIPATION (35 U.S.C § 102)

Each of the rejected claims has been rejected on the basis of anticipation. To anticipate a claim, a reference must disclose every element of that claim, expressly or inherently, and arranged as called for by the claim.

Claim 29

Reconsideration if requested of the rejection of claim 29 as anticipated by Parasher '756 or by Cragg '653. Parasher fails to disclose a number of limitations in claim 9. Parasher does not relate to an arthroscopically insertable device nor is it a device for arthroscopic therapeutic of a joint to remove irritant fragments from a joint. Parasher discloses a flexible catheter, and cannot be considered as having the claimed shaft that is relatively rigid for most of its length. Parasher does not disclose an arrangement in which the rigidity of a shaft is sufficient to enable it to bring a debridement tip to bear forcefully against select internal regions of a joint.

Reconsideration also is requested of the rejection of claim 29 as anticipated by Cragg '653. Cragg is directed to an arrangement for dissolving newly-formed soft

thrombus in a blood vessel. It does not relate to an arthroscopically insertable device for treatment of a joint nor is it adapted to remove irritant fragments from a joint. The Cragg device, as Parasher, includes an elongate flexible shaft, not a relatively rigid shaft with a flexible debridement tip, as called for by the claim. To the extent that the rejection was based on the notion that the shaft 14 in Cragg corresponds to applicants' claimed shaft, the Cragg drive shaft necessarily must be flexible in order to be navigated through blood vessels that necessarily are curved. Indeed, the preferred diameter for the wire drive shaft 14 is about 0.50 ml. Cragg does not disclose the relatively rigid shaft.

Neither of Parasher nor Cragg discloses these features. The rejection under 35 U.S.C. § 102 is improper.

Claims 30-36

Reconsideration is requested of each of the rejections. **Claims 30-36** as anticipated by Cragg. Each of these claims depends directly or indirectly from claim 29 and is not anticipated by Cragg for the same reasons. Additionally, claims 30-36 include additional limitations that are missing from Cragg and provide additional reasons by Cragg does not anticipate. For example, **claim 30** includes the additional limitation of a lumen extending through the rigid shaft having at least one emission outlet in the debridement tip to enable pressurized liquid streams at sufficient velocity and impact force to facilitate debridement. Although one of the embodiments in Cragg discloses a shaft having a lumen that terminates in distal outlet ports, the rate of liquid infusion in Cragg is extremely low, between 2-250 ml/hour. That is essentially little more than a drip rate of flow and does not suggest that a pressurized liquid stream with a velocity

and impact force to facilitate debridement. **Claim 32** includes the further limitation that at least one of the emission outlets is oriented to direct emitted liquid in a generally distal direction. The hollow drive shaft, 44, of Cragg is not described as having a distally directed emission outlet. **Claim 33** includes limitations to the molded polymer tip and its cross sectional dimensions in combination with the bristles and that the bristles do not extend substantially beyond the cross sectional dimension of the shaft. In Cragg, the bristles of all the brushes extend well beyond the cross sectional dimension of the shaft 14, 44. **Claim 35** includes the limitation that the bristles are molded integrally with the tip and claim 36 includes a limitation that the tip is molded to include an internal chamber that communicates with the lumen of the shaft. Cragg does not disclose either of these additional features.

Claim 40 includes the limitation that the bristles extend from at least one surface of the tip that is disposed radially inwardly of the more proximal portion of the tip. No such feature is disclosed in Cragg.

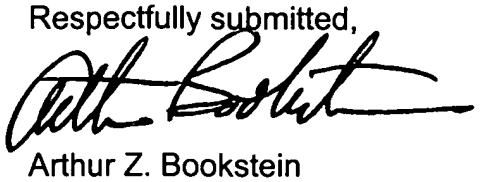
Claims 40-47

Reconsideration is requested of the rejection of claim 41 as anticipated by either or Parasher or Cragg. Each of claims 41-47 depends directly or indirectly from claim 29 and is not anticipated by either Parasher or Cragg for the same reasons. **Claim 41** includes a limitation that the shaft has an outer sleeve formed integrally with and from the same material as the debrider as the stiffening tube disposed within the sleeve. Neither Parasher nor Cragg discloses such an arrangement. The element 80 in Cragg, referred to as disclosing the claim stiffening tube is, in fact, another catheter said to have an expandable balloon 82. (see Cragg at 8:23-48)

Reconsideration if requested of the rejection claim 42 is anticipated by Cragg. **Claim 42** includes the additional limitation that the debriding surface does not extend substantially beyond the radially dimensions defined by the shaft. Clearly, Cragg, the radial dimensions of the cytology brush are substantially greater than that of anything that can be considered as a shaft. **Claim 43** depends from claim 42 and as the further limitation that the debrider as recessed surface from which the bristles extend. Cragg discloses no such feature. **Claim 44** specifies an outer limit beyond which the debriding surface of the debrider does not extend radially beyond the transverse cross sectional dimension of the shaft. Again, Cragg discloses no such feature.

Reconsideration is requested of the rejection of each of claims 46 and 47 as anticipated by either Parasher or Cragg. Claim 46 depends from claim 29 and is not anticipated for the same reasons. Additionally, claim 46 includes limitations directed to a knob mounted to the shaft by which the connector can be rotated relative to the hand piece. No such feature is disclosed in either Cragg or Parasher. **Claim 47** includes the additional limitation that the juncture of the debrider and the shaft is substantially smooth to facilitate entry and removal of the tip fro the joint. Here, again, this feature is not disclosed either by Cragg or by Parasher.

Respectfully submitted,



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